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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,763	03/03/2004	Kunio Moriyama	K2020.0005/P005	5136
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DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP			LEYBOURNE, JAMES J	
2101 L Street, NW			ART UNIT	
Washington, DC 20037			PAPER NUMBER	
			2881	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/790,763

Applicant(s)

MORIYAMA ET AL.

Examiner

James J. Leybourne

Art Unit

2881

mw

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/3/04; 7/11/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Claim Objections***

1. Claim 26 is objected to because of the following informalities: In line . "44" should be "4" because it is a typographical errors. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lesyna et al. (USPN 5260581).

Regarding claims 1, 2, 3, 4, 6, 8, 14, 16, 17, 18 in Fig. 1, Lesyna et al. disclose a particle beam therapy system comprising:

- a charged particle beam generator for emitting a charged particle beam (SOURCE 10)
- a plurality of treatment rooms in each of which an irradiation unit for irradiating the charged particle beam is disposed;
- a plurality of beam transport systems communicated with said charged particle beam generator and transporting the charged particle beam emitted from said charged particle beam generator separately to respective irradiation units in said plurality of treatment rooms
- a plurality of electromagnets, [38, 40 etc.] disposed in the beam path

It is well known in the art that the system must be controlled such that, for each patient, treatment must be precisely controlled in accordance with the treatment by the physician (treatment plan information) specified and must be based on patient identification. This would inherently require treatment plan information specified depending on patient identification information and knowledge of which patient is in a particular treatment room (patient identification).

Regarding claims 1 and 2, the proton beam therapy system is under operator control via a computer control system such as illustrated in FIG.6 (column 2, lines 24-27) that accepts information and generates control information for a plurality of elements provided in the beam transport system introducing the charged particle beam to the irradiation unit in the selected treatment room.

Regarding claim 3, as seen in Fig. 1, there is a path switching device at each of junctions between the beam path of the first beam transport system (from the source to element 38) and beam paths in the second beam transport systems.

Regarding claim 4, at the treatment stations 18, 20 and 22, the beam transport system 16 includes gantries 28, 30 and 32 respectively, carrying optics for receiving a proton beam on its axis of rotation, transporting the proton beam away from the axis of rotation and returning the proton beam on a path perpendicular to and intersecting the axis of rotation at a patient supported in a fixed orientation by a patient support, such as table 34 (column 2, lines 27-39).

Regarding claims 5, 7, 9 and 10, the beam request signal agrees with the beam path configuration signal and the beam configuration request agrees with the accelerator beam configuration signal for a particular treatment room. The method illustrated in FIG. 4 includes a further step within the selection verification process namely, the gating of treatment room configuration signals with the treatment room selection signal. Thus, control command information only uses control information for the selected treatment room.

Regarding claims 6, 8 and 18, it is inherent that information for the charged particle beam exiting from the charged particle beam accelerator and excitation information for a plurality of electromagnets disposed in the beam path will be used. The entire system is under regulation and operator control through a control system such as illustrated in FIG. 6 (column 4, lines 37-39).

Regarding claims 11-13, the MASSCOMP performs the centralized coordination of beam requests from the treatment stations in the therapy system as well as programmed beam-energy for storing operating conditions and copies of the data bases used in the local stations (column 4, lines 47-51).

With respect to claims 15, 20, 21, 22, 26 and 30, Lesyna et al. show a controller and control system for the charged particle treatment system using status information from the various system components. A system configuration providing treatment room selection verification and control of beam path configuration and beam configuration is depicted diagrammatically in FIG. 5. As represented, the system includes a plurality of treatment rooms #1 through #N each including a computer 100 for generating a beam request signal, a beam configuration request signal, and treatment room configuration signals. Such signals are applied to a comparator and gating module 102 for processing. The beam request signals and the beam configuration request signals are also supplied to a master computer system 104, such as the MASSCOMP 94 illustrated in FIG. 6. In response to the beam request signals and beam configuration signals from each of the treatment rooms, the master computer system will determine which of the request signals, if any, will control the settings of the magnets in the switchyard and the settings of the magnets, RF circuits and the extraction septum in the accelerator to determine the beam path within the switchyard and the configuration of the beam exiting the accelerator. In the system illustrated in FIG. 5, the output of the master computer system 104 comprise setting signals for the accelerator magnets and beam configuration components represented generally as accelerator beam controllers #1 though #N, each of which has associated therewith a detector or monitor for developing

a signal indicative of the status of its associated controller. Such signals combine in the comparator **102** to define an accelerator beam configuration signal indicative of the configuration of the beam generated by the accelerator for a particular setting of the various beam controllers for the accelerator.

In a like manner, the output of the master computer system **104** comprises setting signals for the various magnets included in the switchyard, indicated diagrammatically as magnets **#1** through **#N**. Each of such magnets includes an associated detector or monitor which generates a signal indicative of the state of the magnet with which it is associated. Such signals are applied to the comparator and gating module **102** to define the switchyard path configuration signal from the switchyard. As previously described, such switchyard path configuration and beam configuration signals are compared in the comparator **102** with the request signals generated by the various treatment rooms. Upon finding an agreement between the treatment room beam request and configuration signals with the switchyard beam path configuration and accelerator beam configuration signals, the comparator develops a treatment room selection signal utilized as beam authorization signals to the switchyard and accelerator, provided that the treatment room configuration signals indicate that the treatment room is ready to receive beams with all enabling conditions being met and all beam halting and aborting conditions not being present. In the latter situation, the comparator develops a beam halting signal which denies beam from the accelerator to the switchyard and hence to any of the treatment rooms. As previously described, such treatment configuration signals are generated in each of the treatment rooms and are applied to the comparator and gating module **102** as illustrated.

The COMPARATOR AND GATING MODULE **102** preferably comprises a plurality of gates and registers for comparing and processing the various signals applied as inputs. Such comparator modules are well known in the art and may be readily

developed by those of ordinary skill in the art considering the design parameters set forth in this specification (column 7, line 37 through column 8, line 40.)

With respect to claims 23, 24, 25, the COMPARATOR AND GATING MODULE 102 emits a beam authorization signal (Fig. 5).

Regarding claim 19, the control method for the system is shown in Figs. 3 and 4.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesyna et al. as applied to claims 1-26 above in view of Donnadille (USPN 3963935). Lesyna et al. do not teach using shutters located in the treatment rooms. Donnadille discloses a shutter designed for temporarily closing off an opening formed in the wall of an irradiation room, for the passage of a particle beam. It would be obvious to one of ordinary skill in the art at the time of the invention to modify the system of Lesyna et al. to include the shutters of Donnadille because Donnadille teaches when irradiation rooms are not in use, the safety aspect requires that permanent monitoring of the absence of all irradiation there is necessary. To do this, precautions must be taken and in particular the opening formed in the irradiation room for the passage of the particle

beam must be closed off completely by means of a shutter whenever the room is not in use (column 1, lines 13-21).

***Relevant Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. The following patents are cited to show further show the state of the art with respect to beam control in a particle beam therapy system comprising multiple treatment rooms.

Moriyama et al. (2004/0183033)

Martin (USPN 5,073,913)

Morgan et al. (USPN 6,444,990).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James J. Leybourne whose telephone number is 571 262-2478. The examiner can normally be reached on M\_F 10:00AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee can be reached on 571 272-2477. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).




Application/Control Number:  
10/790,763  
Art Unit: 2881

Page 8

September 24, 2005

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